FEB 11 2008

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K073490

1.	Submitter name, address, contact	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034	
		U.S. Telephone: U.S. Fax:	469-230-0959 972-317-7861
		Contact Person:	Stephanie G. Donnelly
		Date Prepared:	December 10, 2007
2.	Device name	Proprietary Name:	Olympus IgG Reagent (OSR6X172)
		Common Name:	IgG Reagent
		Classification Name:	IgG, Antigen, Antiserum, Control
3.	Predicate device(s)	Serum/Plasma Applications	Olympus (OSR6145) IgG Reagent Submitted (K951013)
		CSF Application	Roche Tina-Quant IgG GEN.2 Submitted (K050113)

4. Device description

In this Olympus procedure:

- When a sample is mixed with R1 buffer and R2 antiserum solution, human IgG reacts specifically with anti-human IgG antibodies to yield insoluble aggregates.
- Immune complexes formed in solution scatter light in proportion to their size, shape and concentration.
- Turbidimeters measure the reduction of incidence light due to reflection, absorption or scatter.
- In the Olympus procedure, the decrease in intensity of light transmitted (increase in absorbance) through particles suspended in solution is as a result of complexes formed during the antigen-antibody reaction.

5. Intended use

System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on OLYMPUS analyzers.

For *in vitro* diagnostic use.

6. The following tables compare the new Olympus IgG (OSR6X172) reagent with the predicate devices outlined in point 3 above.

Serum/Plasma Applications

Similarities		
Item	Olympus IgG (OSR6X172) reagent	Predicate System
Intended Use	System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on OLYMPUS analyzers.	System reagent for the quantitative determination of IgG immunoglobulins in human serum on OLYMPUS analyzers.
Measurement	Quantitative	Same
Instrument Required	Olympus AU400/400^e, 600/640/640^e and 2700/5400	Same
Reagent handling	Ready for use	Same
Assay Methodology/Operating Principle	Immunoturbidimetric	Same
Reagent storage form	Liquid On –board storage	Same
Calibration	Olympus Serum Protein Mulit-Calibrator (ODR3021)	Same
Calibration Traceability	This method is traceable to the International Reference Preparation CRM 470 (US designation RPPHS lot 91/0619)	Same
Antibody	Goat Anti-IgG antiserum	Same
Expected Values	635-1741 mg/dL	Same
Reagent On Board Stability	Opened reagents are stable for 90 days when stored in the refrigerated compartment of the analyzer.	Same
Calibration Frequency	90 days	Same

Differences		
Item	Olympus IgG (OSR6X172) reagent	Predicate System
Specimen Type	Serum, Li-heparin or EDTA plasma: and cerebrospinal fluid	Serum

Performance Characteristics		
Item	Olympus IgG (OSR6X172) reagent	Predicate System
Assay Range	75-3000 mg/dL	75-3000 mg/dL
LoQ	75 mg/dL	Not specified
Prozone Capacity	No high dose effect at IgG concentrations up to 30,000 mg/dL	Not specified
Precision	AU400/400^e Sample Total CV% 1 2.18 2 2.29 3 3.43 AU600/640/640^e Sample Total CV% 1 3.29 2 3.49 3 4.66	AU400/400^e Sample Total CV% 1 0.82 2 1.06 3 2.24 AU600 Sample Total CV% 1 2.50 2 1.54 3 1.92

	AU2700/5400 Sample Total CV% 1 1.51 2 1.87 3 2.03	AU640/640[e] Sample Total CV% 1 1.00 2 1.00 AU2700/5400 Sample Total CV% 1 1.54 2 2.39 3 2.84
Method Comparison (Linear Regression)	Intercept 37.2 Slope 0.945 R^2 0.998 n 120 Range 195-2986 mg/dL	Intercept -117 Slope 1.086 R^2 0.993 n 98 Range 223-2633 mg/dL
Interfering Substances	AU400/400[e] Bilirubin: Interference less than 2% up to 40 mg/dL Bilirubin Hemolysate: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 3% up to 1000 mg/dL Intralipid RF: Interferences less than 7% up to 1200 IU/mL Not tested AU600/640/640[e] Bilirubin: Interference less than 3% up to 40 mg/dL Bilirubin Hemolysate: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 5% up to 1000 mg/dL Intralipid RF: Interferences less than 7% up to 1200 IU/mL Not tested AU2700/5400 Bilirubin: Interference less than 1% up to 40 mg/dL Bilirubin Hemolysate: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 2% up to 1000 mg/dL Intralipid RF: Interferences less than 7% up to 1200 IU/mL Not tested	AU400/400[e] Bilirubin: Interference less than 1% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 2% up to 500 mg/dL Hemolysate Lipemia: Interference less than/10% up to 1000 mg/dL Intralipid. RF: Not Specified Ascorbic acid: Interference less than 1% up to 20 mg/dL Ascorbate AU600/640/640[e] Bilirubin: Interference less than 2% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 2% up to 500 mg/dL Hemolysate Lipemia: Interference less than 3% up to 1000 mg/dL Intralipid. RF: Not Specified Ascorbic acid: Interference less than 2% up to 20 mg/dL Ascorbate AU2700/5400 Bilirubin: Interference less than 5% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 3% up to 1000 mg/dL Intralipid. RF: Not Specified Ascorbic acid: Interference less than 3% up to 20 mg/dL Ascorbate

CSF Application

Similarities		
Item	Olympus IgG (OSR6X172) reagent	Predicate Systems
Intended Use	System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on OLYMPUS analyzers.	In vitro test for the quantitative determination of IgG in human serum, plasma and cerebrospinal on Roche/Hitachi Cobas c systems.
Measurement	Quantitative	Same
Specimen Type	Serum, plasma: Li-heparin or EDTA and cerebrospinal fluid	Same
Antibody	Goat Anti-IgG antiserum	Same
Reagent handling	Ready for use	Same
Assay Methodology/Operating Principle	Immunoturbidimetric	Same
Reagent storage form	Liquid On –board storage	Same
Calibration Traceability	CRM 470	Same
Calibration	Multi-point	Same

Differences		
Item	Olympus IgG (OSR6X172) reagent	Predicate System
Instrument Required	Olympus AU400/400^{e}, 600/640/640^{e} and 2700/5400	Roche/Hitachi Cobas c systems.
Expected Values	15 – 20 y 3.5 mg/dL ± 2.0 mg/dL 21 – 40 y 4.2 mg/dL ± 1.4 mg/dL 41 – 60 y 4.7 mg/dL ± 1.0 mg/dL	1-3 mg/dL
Reagent On Board Stability	Opened reagents are stable for 90 days when stored in the refrigerated compartment of the analyzer.	Opened reagents are stable for 84 days when stored in the refrigerated compartment of the analyzer.
Calibration	Olympus Serum Protein Mulit-Calibrator (ODR3021)	S1 H_2O S2 C.f.a.s. PUC
Calibration Frequency	2 Days	Not Specified

Performance Characteristics		
Item	Olympus IgG (OSR6X172) reagent	Predicate System
Assay Range	2-50 mg/dL	0.4-20 mg/dL
LoQ	2 mg/dL	Not specified
Prozone Capacity	No high dose effect at IgG concentrations up to 6,000 mg/dL	No high dose effect at IgG concentrations up to 100 mg/dL
Precision	AU400/400^{e} Sample Total CV% 1 9.82 2 4.08 3 3.61 AU600/640/640^{e} Sample Total CV% 1 9.53 2 3.67 3 2.81 AU2700/5400 Sample Total CV% 1 10.24 2 6.29 3 3.83	Sample Total CV% 1 2.1 2 1.1

Method Comparison (Linear Regression)	Intercept -0.069 Slope 1.067 R^2 0.998 Range 2.0-42.9 mg/dL	Intercept -0.17 Slope 0.997 R^2 1.000 Range 1.07-18.6 mg/dL
Interfering Substances	AU400/400^e/600/640/640^e/2700/5400 Bilirubin: Interference less than 10% up to 36 mg/dL Bilirubin Hemolysis: Interference less than 10% up to 500 mgdL Hemolysate	Bilirubin: Interference less than 10% up to 15 mg/dL Bilirubin Hemolysis: Interference less than 10% up to 200 mg/dL Hemolysate

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 11 2008

Olympus America, Inc.
c/o Ms. Stephanie Donnelly
Regulatory Affairs/Quality Assurance Manager
Olympus Life Science Research Europa GmbH
Lismeehan, O, Callaghan's Mills
Co. Claire, Ireland.

Re: k073490
Trade/Device Name: Olympus IgG reagent
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, E immunological test systems
Regulatory Class: Class II
Product Code: CFN
Dated: December 11, 2007
Received: December 12, 2007

Dear Ms. Donnelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073490

Device Name: The Olympus IgG reagent (OSR6X172).

Indication For Use: System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on OLYMPUS analyzers.

The measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

For *in vitro* diagnostic use.

Prescription Use ___✓___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073490